

AMENDED IN SENATE JULY 1, 2015
AMENDED IN ASSEMBLY MAY 6, 2015
AMENDED IN ASSEMBLY MARCH 26, 2015
CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1069

Introduced by Assembly Member Gordon
(Coauthors: Assembly Members Chu, Low, and Mark Stone)
(Coauthors: Senators Beall and Wieckowski)

February 26, 2015

An act to amend Section 150204 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 1069, as amended, Gordon. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish a repository and distribution program under which a pharmacy, including a pharmacy that is owned by, or contracts with, the county, may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that establishes a depository and redistribution program to develop written procedures for, among other things, establishing eligibility for medically indigent patients who may participate in the program, and ensuring that patients eligible for the program are not charged for any medications provided under the program. Existing law also prohibits the donation of controlled substances to the repository and distribution program. Under existing law, only medication that is donated in unopened, tamper-evident packaging or modified unit dose

containers that meet the United States Pharmacopoeia standards, and that includes lot numbers and expiration dates, is eligible for donation to the program. Existing law authorizes a county-owned pharmacy participating in the program to transfer eligible donated medication to a county-owned pharmacy participating in the program within another adjacent county, as specified. Existing law prohibits medication that does not meet the requirements for donation and distribution from being sold, dispensed, or otherwise transferred to any other entity. Existing law requires medication donated to the repository and distribution program to be maintained in the donated packaging units.

This bill would authorize ~~a county-owned pharmacy~~ *an entity* participating in the medication repository and distribution program to transfer eligible donated medication to a participating ~~county-owned pharmacy~~ *entity* in any other county, as specified. *The bill would generally prohibit an entity from transferring more than 15% of its donated medications annually.* The bill would authorize medication donated to a medication repository and distribution program to be maintained in new, properly labeled ~~containers~~ *containers, as specified.* The bill would prohibit donated medication from being repackaged more than 2 times. This bill would also make a technical, nonsubstantive change to these provisions.

Vote: majority. Appropriation: no. Fiscal committee: no.
State-mandated local program: no.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 150204 of the Health and Safety Code
- 2 is amended to read:
- 3 150204. (a) (1) A county may establish, by an action of the
- 4 county board of supervisors or by an action of the public health
- 5 officer of the county, as directed by the county board of
- 6 supervisors, a repository and distribution program for purposes of
- 7 this division. The county shall advise the California State Board
- 8 of Pharmacy within 30 days from the date it establishes a repository
- 9 and distribution program.
- 10 (2) Only an eligible entity, pursuant to Section 150201, may
- 11 participate in this program to dispense medication donated to the
- 12 drug repository and distribution program.
- 13 (3) An eligible entity that seeks to participate in the program
- 14 shall inform the county health department and the California State

1 Board of Pharmacy in writing of its intent to participate in the
2 program. An eligible entity may not participate in the program
3 until it has received written or electronic documentation from the
4 county health department confirming that the department has
5 received its notice of intent.

6 (4) (A) A participating entity shall disclose to the county health
7 department on a quarterly basis the name and location of the source
8 of all donated medication it receives.

9 (B) A participating primary care clinic, as described in Section
10 150201, shall disclose to the county health department the name
11 of the licensed physician who shall be accountable to the California
12 State Board of Pharmacy for the clinic's program operations
13 pursuant to this division. This physician shall be the professional
14 director, as defined in subdivision (c) of Section 4182 of the
15 Business and Professions Code.

16 (C) The county board of supervisors or public health officer of
17 the county shall, upon request, make available to the California
18 State Board of Pharmacy the information in this division.

19 (5) The county board of supervisors, the public health officer
20 of the county, and the California State Board of Pharmacy may
21 prohibit an eligible or participating entity from participating in the
22 program if the entity does not comply with the provisions of the
23 program, pursuant to this division. If the county board of
24 supervisors, the public health officer of the county, or the California
25 State Board of Pharmacy prohibits an eligible or participating
26 entity from participating in the program, it shall provide written
27 notice to the prohibited entity within 15 days of making this
28 determination. The county board of supervisors, the public health
29 officer of the county, and the California State Board of Pharmacy
30 shall ensure that this notice also is provided to one another.

31 (b) A county that elects to establish a repository and distribution
32 program pursuant to this division shall establish written procedures
33 for, at a minimum, all of the following:

34 (1) Establishing eligibility for medically indigent patients who
35 may participate in the program.

36 (2) Ensuring that patients eligible for the program shall not be
37 charged for any medications provided under the program.

38 (3) Developing a formulary of medications appropriate for the
39 repository and distribution program.

1 (4) Ensuring proper safety and management of any medications
2 collected by and maintained under the authority of a participating
3 entity.

4 (5) Ensuring the privacy of individuals for whom the medication
5 was originally prescribed.

6 (c) Any medication donated to the repository and distribution
7 program shall comply with the requirements specified in this
8 division. Medication donated to the repository and distribution
9 program shall meet all of the following criteria:

10 (1) The medication shall not be a controlled substance.

11 (2) The medication shall not have been adulterated, misbranded,
12 or stored under conditions contrary to standards set by the United
13 States Pharmacopoeia (USP) or the product manufacturer.

14 (3) The medication shall not have been in the possession of a
15 patient or any individual member of the public, and in the case of
16 medications donated by a health or care facility, as described in
17 Section 150202, shall have been under the control of a staff
18 member of the health or care facility who is licensed in California
19 as a health care professional or has completed, at a minimum, the
20 training requirements specified in Section 1569.69.

21 (d) (1) Only medication that is donated in unopened,
22 tamper-evident packaging or modified unit dose containers that
23 meet USP standards is eligible for donation to the repository and
24 distribution program, provided lot numbers and expiration dates
25 are affixed. Medication donated in opened containers shall not be
26 dispensed by the repository and distribution program, and once
27 identified, shall be quarantined immediately and handled and
28 disposed of in accordance with the Medical Waste Management
29 Act (Part 14 (commencing with Section 117600) of Division 104).

30 (2) (A) A medication that is the subject of a United States Food
31 and Drug Administration managed risk evaluation and mitigation
32 strategy pursuant to Section 355-1 of Title 21 of the United States
33 Code shall not be donated if this inventory transfer is prohibited
34 by that strategy, or if the inventory transfer requires prior
35 authorization from the manufacturer of the medication.

36 (B) A medication that is the subject of a United States Food and
37 Drug Administration managed risk evaluation and mitigation
38 strategy pursuant to Section 355-1 of Title 21 of the United States
39 Code, the donation of which is not prohibited pursuant to

1 subparagraph (A), shall be managed and dispensed according to
2 the requirements of that strategy.

3 (e) A pharmacist or physician at a participating entity shall use
4 his or her professional judgment in determining whether donated
5 medication meets the standards of this division before accepting
6 or dispensing any medication under the repository and distribution
7 program.

8 (f) A pharmacist or physician shall adhere to standard pharmacy
9 practices, as required by state and federal law, when dispensing
10 all medications.

11 (g) Medication that is donated to the repository and distribution
12 program shall be handled in the following ways:

13 (1) Dispensed to an eligible patient.

14 (2) Destroyed.

15 (3) Returned to a reverse distributor or licensed waste hauler.

16 (4) (A) Transferred to another participating entity within the
17 county to be dispensed to eligible patients pursuant to this division.
18 Notwithstanding this paragraph, a ~~participating-county-owned~~
19 ~~pharmacy entity~~ may transfer eligible donated medication to a
20 ~~participating-county-owned pharmacy entity~~ within another county
21 that has adopted a program pursuant to this division, if the
22 ~~pharmacies participating entities~~ transferring the medication have
23 a written agreement ~~between the entities~~ that outlines protocols
24 and procedures for safe and appropriate drug transfer that are
25 consistent with this division. *A participating entity shall not*
26 *transfer more than 15 percent of its donated medications annually*
27 *unless the transfer is performed pursuant to Section 4126.5 of the*
28 *Business and Professions Code.*

29 (B) Medication donated under this division shall not be
30 transferred by any participating entity more than once, and after
31 it has been transferred, shall be dispensed to an eligible patient,
32 destroyed, or returned to a reverse distributor or licensed waste
33 hauler.

34 (C) Medication transferred pursuant to this paragraph shall be
35 transferred with documentation that identifies the drug name,
36 strength, and quantity of the medication, and the donation facility
37 from where the medication originated shall be identified on
38 medication packaging or in accompanying documentation. The
39 document shall include a statement that the medication may not
40 be transferred to another participating entity and must be handled

1 pursuant to subparagraph (B). A copy of this document shall be
2 kept by the participating entity transferring the medication and the
3 participating entity receiving the medication.

4 (h) Medication that is donated to the repository and distribution
5 program that does not meet the requirements of this division shall
6 not be distributed or transferred under this program and shall be
7 either destroyed or returned to a reverse distributor. Donated
8 medication that does not meet the requirements of this division
9 shall not be sold, dispensed, or otherwise transferred to any other
10 entity.

11 (i) (1) Medication donated to the repository and distribution
12 program shall be maintained in the donated packaging units or
13 new, properly labeled containers until dispensed to an eligible
14 patient under this program, who presents a valid prescription. When
15 dispensed to an eligible patient under this program, the medication
16 shall be in a new and properly labeled container, specific to the
17 eligible patient and ensuring the privacy of the individuals for
18 whom the medication was initially dispensed. Expired medication
19 shall not be dispensed. Donated medication shall not be repackaged
20 more than two times. Nothing in this section requires donated
21 medication to be repackaged two times.

22 (2) *All of the following requirements shall be satisfied when*
23 *repackaging donated medication:*

24 (A) *Medication shall be repackaged into a container that holds*
25 *an individual prescription for a supply of no more than 90 days.*

26 (B) *Repackaged medication shall be identifiable as donated*
27 *medication.*

28 (C) *Repackaged medication shall be labeled with all of the*
29 *following:*

30 (i) *All applicable lot numbers.*

31 (ii) *The earliest expiration date.*

32 (iii) *The number of times that the medication has been*
33 *repackaged.*

34 (j) Medication donated to the repository and distribution program
35 shall be segregated from the participating entity's other drug stock
36 by physical means, for purposes including, but not limited to,
37 inventory, accounting, and inspection.

38 (k) A participating entity shall keep complete records of the
39 acquisition and disposition of medication donated to, and
40 transferred, dispensed, and destroyed under, the repository and

1 distribution program. These records shall be kept separate from
2 the participating entity's other acquisition and disposition records
3 and shall conform to the Pharmacy Law (Chapter 9 (commencing
4 with Section 4000) of Division 2 of the Business and Professions
5 Code), including being readily retrievable.

6 (l) Local and county protocols established pursuant to this
7 division shall conform to the Pharmacy Law regarding packaging,
8 transporting, storing, and dispensing all medications.

9 (m) County protocols established for packaging, transporting,
10 storing, and dispensing medications that require refrigeration,
11 including, but not limited to, any biological product as defined in
12 Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262),
13 an intravenously injected drug, or an infused drug, shall include
14 specific procedures to ensure that these medications are packaged,
15 transported, stored, and dispensed at appropriate temperatures and
16 in accordance with USP standards and the Pharmacy Law.

17 (n) Notwithstanding any other provision of law, a participating
18 entity shall follow the same procedural drug pedigree requirements
19 for donated drugs as it would follow for drugs purchased from a
20 wholesaler or directly from a drug manufacturer.